## **Enrollment: Pancreas**

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Fissue Source Site (TSS) Name:	HCMI Identifier (ID3):
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**Form Notes:** An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2		2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3		5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Info		T	T	T
4	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
5	Height		649	Provide the patient's height, in centimeters.
6	Weight		651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)		2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
8	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories.  American Indian or Alaska Native: A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.  Asian: A person having origins in any of the peoples of the Far East, Southeast Asia, or in the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.  Black or African American: A person having origins in any of the black racial groups of Africa.  Native Hawaiian or other Pacific Islander: A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island.  White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
9	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories.  Hispanic or Latino: A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.  Not Hispanic or Latino: A person not meeting the definition of Hispanic or Latino.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
10	Number of days from index date to date of last contact		3008273	Provide the number of days from the index date to the date of last contact.
11	Patient age on index date		6379572	Provide the age (in days) of the patient on the index date.  Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.
12	Year of birth		2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	<ul> <li>Lifelong non-smoker (&lt;100 cigarettes smoked in a lifetime)</li> <li>Current smoker (includes daily and non-daily smokers)</li> <li>Current reformed smoker (duration not specified)</li> <li>Current reformed smoker for &gt;15 years</li> <li>Current reformed smoker for ≤15 years</li> </ul>	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Metastasis at diagnosis assessment status	<ul><li>☐ Metastatic</li><li>☐ Non-metastatic (confirmed)</li><li>☐ Non-metastatic (unconfirmed)</li></ul>	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor.  Note: If metastatic at diagnosis, proceed to Question 16, otherwise, skip to Question 17.
16	Metastatic site(s) at diagnosis	☐ Liver ☐ Lung ☐ Peritoneum ☐ Other (specify)	3029815	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor.  Note: If the anatomic site of tumor tissue is not listed, proceed to Question 16a, otherwise, skip to Question 17.
16a	Specify metastatic site(s)		3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
17	Alcohol exposure intensity	☐ Drinker ☐ Heavy drinker ☐ Lifetime non-drinker ☐ Non-drinker ☐ Occasional drinker ☐ Not evaluated	3457767	Select the patient's current level of alcohol use as self-reported by the patient.
18	Amount of alcohol consumption per week		3114013	Provide the average number of days each week that the patient consumes an alcoholic beverage.
19	History of diabetes	☐ Yes ☐ No ☐ Unknown	3197322	Indicate whether the patient has a diagnosis of diabetes. Note: If the patient does not have a history of diabetes, skip to Question 22.
20	Number of days from the index date to the date of diabetes onset		3457768	Provide the number of days from the index date to the date the patient was diagnosed with diabetes.
21	Diabetes treatment	☐ Injected insulin ☐ Biguanide ☐ Sulfonylurea ☐ Thiazolidinedione ☐ Alpha-glucosidase inhibitor ☐ Other (specify)	3587247	Select all diabetes mellitus treatments given to the patient. Note: If the diabetes treatment is not listed, proceed to Question 21a, otherwise, skip to Question 22.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
21a	Other diabetes treatment		3587240	If the patient's diabetes treatment is not included on the previous list, provide the name of the other diabetes treatment.
22	Prior clinical history, if known	<ul> <li>□ IPMN</li> <li>□ Chronic pancreatitis</li> <li>□ Neuroendocrine tumor</li> <li>□ Adenocarcinoma</li> <li>□ Not applicable</li> <li>□ Unknown</li> </ul>	5983086	Provide the patient's clinical history that may increase risk of pancreatic cancer.
23	Basis of diagnosis of prior clinical history	<ul><li>☐ Histologic</li><li>☐ Pathologic</li><li>☐ Radiologic</li><li>☐ Not applicable</li></ul>	5946730	Select the method used to determine the diagnosis of prior clinical history.
24	History of clinical chronic pancreatitis	☐ Yes ☐ No	3457760	Indicate whether or not the patient has a history of clinical chronic pancreatitis.  Note: If the patient does not have a history of chronic pancreatitis, skip to Question 26.
25	Year of chronic pancreatitis diagnosis		3457763	Provide the year that the patient was diagnosed with clinical chronic pancreatitis.
Biospecime	n Information		-	<u> </u>
26	Tissue sample type(s) collected for HCMI for this case	□ Normal tissue □ Primary tumor □ Metastatic □ Recurren □ Other tiss		Please select all the tissue sample types submitted for HCMI with this case.
27	Number of NORMAL tissues biospecimens collected for HCMI for this case		6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case.  Note: This number is expected to be 1.
28	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case		6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.
29	Number of METASTATIC/RECURRENT cancer tissue biospecimens collected for HCMI model development for this case		6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.
30	Number of OTHER tissue biospecimens collected for HCMI model development for this case		6584259	Please provide the number of pre- malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
31	Total number of tissue biospecimens collected for HCMI for this case		6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. Note: This number should be the sum of the normal, primary tumor, metastatic/ recurrent tumor, and other biospecimen counts above.
Normal Con	trol Information		•	
32	Normal tissue biospecimen ordinal		6584264	Please provide a number to identify which biospecimen this is in the sequence. Note: The first biospecimen should be number "1," the second should be number "2," etc.
33	CMDC sample ID		6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
34	BPC submitter ID (if available)		6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
35	Type of normal control	<ul> <li>□ Whole blood</li> <li>□ Buccal cells</li> <li>□ Buffy coat</li> <li>□ Lymphocytes</li> <li>□ Extracted DNA from blood</li> <li>□ Extracted DNA from saliva</li> <li>□ Extracted DNA from buccal cells</li> <li>□ Extracted DNA from normal tissue</li> <li>□ FFPE non-neoplastic tissue</li> <li>□ Non-neoplastic tissue</li> </ul>	3081936	Indicate the type of normal control submitted for this case.
36	Anatomic site of normal tissue	☐ Duodenum ☐ Gastrointestinal ☐ Pancreas ☐ Skin ☐ Spleen ☐ Other (specify) ☐ Not applicable	4132152	If non-neoplastic tissue was submitted as the normal control, select the anatomic site of the normal tissue.  Note: If the anatomic site of normal tissue is not listed, proceed to Question 36a, otherwise, skip to Question 37.
36a	Other anatomic site of normal tissue		3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
37	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor.  Note: If normal tissue was not submitted, select 'Not applicable'.
38	Normal tissue sample preservation method	☐ Cryopreserved ☐ OCT ☐ FFPE ☐ Snap frozen ☐ Frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
39	nor Biospecimen Information ICD-10 code for primary tumor	□ C25.0 □ C25.7 □ C25.8 □ C25.2 □ C25.9 □ C25.3 □ Other (specify) □ C25.4	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject.  Note: If the ICD-10 code is not listed, proceed to 39a, otherwise, skip to Question 40.

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39a	Other ICD-10 code for	, ,	3226287	If the ICD-10 code for the tumor used to
	primary tumor			generate the model submitted to HCMI
				is not included on the provided list,
		<del></del>		specify the ICD-10 code.
40	Tumor Morphology	□ 8013/3 □ 8453/3 □ 8550/3	3226275	Using the patient's
	1 0,	П 9020/2 Ц 8453/3 П 9551/2		pathology/laboratory report, provide
		П 8035/3		the ICD-O-3 histology code of the
		□ 8041/3 □ 8480/3 □ 8576/3 □ 8490/3 □ 8071/2		primary tumor.  Note: If the ICD-O-3 histology code of the
		$\square$ 8246/3 $\square$ 8500/3 $\square$ 89/1/3		primary tumor is not listed, proceed to
		□ 8441/3 □ 8510/3 □ Other (specify)		Question 40a, otherwise, skip to Question
400	Consification	(specify)	2226275	41.
40a	Specify other morphology		3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary
	morphology			tumor is not included on the previous
				list, provide the ICD-O-3 histology code.
41	Tissue or organ of origin	☐ Pancreas	3427536	Using the patient's
		☐ Other (specify)		pathology/laboratory report, select the
				primary site of the disease. Note: If the primary site of the disease is not listed,
				proceed to Question 41a, otherwise skip to
44-	Other tierre en en en en en	D Abdenies D Other III defined	2427526	Question 42.
41a	Other tissue or organ of origin	☐ Abdomen ☐ Other ill-defined ☐ Accessory sites	3427536	If the primary site of the disease is not included on the previous list, provide
	Oligin	sinus 🗆 Ovary		the primary site of the disease.
		☐ Adrenal gland ☐ Palate		
		☐ Anus ☐ Pancreas		
		☐ Appendix ☐ Penis ☐ Bladder ☐ Peripheral nerves		
		☐ Bone and autonomic		
		☐ Breast nervous system of		
		☐ Connective, trunk		
		subcutaneous		
		and other ☐ Pharynx soft tissues ☐ Pituitary gland		
		☐ Esophagus ☐ Prostate gland		
		☐ Eye ☐ Rectosigmoid		
		☐ Gallbladder junction		
		☐ Gum ☐ Renal pelvis ☐ Head, face or ☐ Retroperitoneum		
		neck		
		☐ Heart ☐ Small intestine		
		☐ Kidney ☐ Spinal cord		
		☐ Larynx ☐ Spleen ☐ Stomach		
		☐ Lip ☐ Stomach ☐ Liver ☐ Testis		
		☐ Lung ☐ Thymus		
		☐ Lymph node ☐ Thyroid gland		
		☐ Male genital ☐ Tongue		
		organs □ Tonsil □ Mediastinum □ Trachea		
		☐ Meninges ☐ Unknown primary		
		☐ Mouth ☐ Urinary system		
		☐ Nasal cavity ☐ Uterus		
		□ Nasopharynx □ Vagina		
		☐ Nervous ☐ Vulva system		
		□ Oropharynx		
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
42	Histological Type	☐ Pancreatic cancer	3081932	Select the surgical pathology text
		☐ Other (specify)		description of the histological tumor type. Note: If the histological tumor type is
				not listed, proceed to Question 42a,
				otherwise, skip to Question 43.
42a	Other histological type		3294805	If the traditional surgical pathology text
				description of the histological tumor type is not included on the previous list,
				please specify the histological type.
43	Histological subtype	☐ Acinar cell carcinoma	3081934	Using the patient's
		☐ Acinar cell cystadenocarcinoma		pathology/laboratory report, select the
		☐ Adenocarcinoma ductal type		histological subtype of the primary
		☐ Hepatoid carcinoma ☐ High-grade neuroendocrine carcinoma		tumor.  Note: If the histological subtype is not
		(large cell type)		listed, proceed to Question 43a, otherwise,
		☐ High-grade neuroendocrine carcinoma		skip to Question 44.
		(small cell type)		
		☐ Inflammatory myofibroblastic tumor		
		☐ Intraductal papillary mucinous neoplasm (IPMN, main duct/mixed)		
		☐ Intraductal papillary mucinous neoplasm		
		(IPMN, side duct)		
		☐ Invasive adenocarcinoma arising from		
		IPMN		
		☐ Invasive carcinoma arising in MCN		
		☐ Medullary carcinoma ☐ Mixed acinar-ductal carcinomas		
		☐ Mixed acinar-neuroendocrine carcinoma		
		☐ Mixed ductal-neuroendocrine carcinoma		
		☐ Mucinous cystic neoplasms (MCN)		
		Pancreas colloid (mucinous non-cystic)		
		carcinoma  Pancreatoblastoma		
		☐ Serous cystic adenoma (SCA)		
		☐ Signet ring cell carcinoma		
		☐ Solid pseudopapillary neoplasm		
		☐ Undifferentiated (anaplastic) carcinoma		
		Undifferentiated carcinoma with osteoclast-like giant cells		
		Unknown		
		☐ Other (specify)		
43a	Other histological		5946219	If the histological subtype for the
	subtype			primary tumor is not included in the
				provided list, specify the histological subtype.
44	Prior malignancy (of the	☐ Yes	5832924	Indicate whether the patient has a
	same cancer type)	□ No		history of prior malignancy of the same
		□ Unknown		cancer type.
45	Prior malignancy (other	☐ Yes	5878828	Indicate whether the patient has a
	cancer type)	□ No □ Unknown		history of prior malignancy of a different cancer type.
46	AJCC cancer staging		2722309	Select the AJCC staging handbook
10	edition	□ 2 <sup>nd</sup> □ 5 <sup>th</sup> □ 8 <sup>th</sup>		edition used to stage the patient's
		□ 3 <sup>rd</sup> □ 6 <sup>th</sup>		primary tumor.
47	AJCC clinical stage group	☐ Stage 0 ☐ Stage IIA	3440332	Using the patient's
		☐ Stage I ☐ Stage IIB		pathology/laboratory report, select the
		☐ Stage IA ☐ Stage III ☐ Stage IV		clinical stage group of the primary tumor as defined by the American Joint
		- Stage is - Stage iv		Committee on Cancer (AJCC).
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48	AJCC pathologic spread: Primary tumor (pT)	□ T0 □ Tis □ T1c □ T4 □ T1a □ T2 □ TX	3045435	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC).
49	AJCC pathologic spread: Lymph nodes (pN)	□ N0 □ N1 □ N2 □ NX	3203106	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC).
50	AJCC pathologic spread: Distant metastases (pM)	<ul> <li>M0</li> <li>M1</li> <li>M1a</li> <li>M1b</li> <li>M1c</li> </ul>	3045439	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).
51	AJCC tumor stage (pathological)	□ Stage 0 □ Stage IIA □ Stage I □ Stage IIB □ Stage 1A □ Stage III □ Stage 1B □ Stage IV	3065862	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the tumor stage as defined by the American Joint Committee on Cancer (AJCC).
52	Tumor grade	☐ G1-Well differentiated ☐ G2-Moderately differentiated ☐ G3-Poorly differentiated ☐ GX-Unknown	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor.
53	Number of peripancreatic lymph nodes tested at surgery		6050944	Provide the total number of peripancreatic lymph nodes tested for the presence of pancreatic cancer cells.
54	Number of positive peripancreatic lymph nodes	□ 0 □ 1-3 □ ≥4 □ Unknown	5983082	Select the numeric range of the number of peripancreatic lymph nodes that tested positive for the presence of pancreatic cancer cells.
55	Has the CEA level of the patient been determined?	☐ Yes ☐ No	3107563	Indicate whether the Carcinoembryonic antigen (CEA) level of the patient has been determined.  Note: If the patient's CEA level has not been determined, skip to Question 58.
56	CEA level		2752	Provide the patient's carcinoembryonic (CEA) level (ng/ml).
57	CEA level upper limit of normal value		2002247	Provide the numeric laboratory value (ng/ml) representing the upper level of the normal range of values for carcinoembryonic antigen (CEA) in blood used to comparatively reference the patient's lab result.
58	Was tumor marker CA- 19-9 test performed?	☐ Yes ☐ No ☐ Unknown	2891778	Indicate whether the patient's tumor marker CA-19-9 value was assessed.  Note: If the CA-19-9 test was not performed, skip to Question 60.
59	What was the CA-19-9 value?		65302	Provide the patient's CA-19-9 level.
Primary Tun	nor Clinical Molecular Charac	cterization		
60	Was KRAS mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6060079	Indicate whether KRAS mutation analysis was performed.  Note: If not performed, skip to Question 61.
61	Was a mutation in KRAS identified	☐ Yes ☐ No	6060081	Indicate whether a mutation in KRAS was identified through mutation analysis. Note: If mutation was not identified, skip to Question 63.

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Question	Question Text	Data Entry Options		CDE ID	Instruction Text
62	If KRAS mutation identified, which one?	☐ G12A ☐ G12V ☐ G13D ☐ G12D ☐ G13R ☐ G13R ☐ G13C	□ G13V □ Q61L □ Q61H □ A146T □ Other (specify)	6060083	Indicate the specific KRAS mutation identified.  Note: If the KRAS mutation is not listed, proceed to Question 62a, otherwise, skip to Question 63.
62a	Other KRAS mutation(s)			6101691	If the KRAS mutation identified is not provided in the previous list, specify the KRAS mutation.
63	Was TP53 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown		6063448	Indicate whether TP53 mutation analysis was performed.  Note: If not performed, skip to Question 65.
64	If TP53 mutation identified, which one?	☐ R213L ☐ R248W ☐ Y220C ☐ G266E ☐ C238Y ☐ G266V	☐ R273H ☐ R273L ☐ R282G ☐ R282W ☐ Other (specify)	6063731	Indicate the specific TP53 mutation identified.  Note: If the TP53 mutation is not listed, proceed to Question 64a, otherwise, skip to Question 65
64a	Other TP53 mutation(s)			6101683	If the TP53 mutation identified is not provided in the previous list, specify the TP53 mutation.
65	Was CDKN2A mutation analysis performed?	☐ Yes☐ No☐ Unknown		6063449	Indicate whether CDKN2A mutation analysis was performed.  Note: If not performed, skip to Question 68.
66	Was a mutation in CDKN2A identified?	☐ Yes ☐ No		6063534	Indicate whether a mutation in CDKN2A was identified through mutation analysis. Note: If mutation was not identified, skip to Question 68.
67	If CDKN2A mutation identified, which one?	□ V51D □ D108H	☐ A147T ☐ A148T ☐ Other (specify)	6063732	Indicate the specific CDKN2A mutation identified. Note: If the CDKN2A mutation is not listed, proceed to Question 67a, otherwise, skip to Question 68.
67a	Other CDKN2A mutation(s)			6101684	If the CDKN2A mutation identified is not provided in the previous list, specify the CDKN2A mutation.
68	Was GNAS mutation analysis performed?	☐ Yes ☐ No ☐ Unknown		6063450	Indicate whether GNAS mutation analysis was performed.  Note: If not performed, skip to Question 71.
69	Was a mutation in GNAS identified?	☐ Yes ☐ No		5983161	Indicate whether a mutation in GNAS was identified through mutation analysis.  Note: If mutation was not identified, skip to Question 71.
70	If GNAS mutation identified, which one?	□ R160C □ R201S	☐ Q227P ☐ Q227R ☐ Other (specify)	6063733	Indicate the specific GNAS mutation identified.  Note: If the GNAS mutation is not listed, proceed to Question 70a, otherwise, skip to Question 71.
70a	Other GNAS mutation(s)			6101685	If the GNAS mutation identified is not provided in the previous list, specify the GNAS mutation.
71	Was RNF43 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown		6063451	Indicate whether RNF43 mutation analysis was performed.  Note: If not performed, skip to Question 72.
72	Was a mutation in RNF43 identified?	☐ Yes ☐ No		5983286	Indicate whether a mutation in RNF43 was identified through mutation analysis.  Note: If mutation was not identified, skip to Question 74.

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Question	Question Text	Data Entry Options		CDE ID	Instruction Text
73	If RNF43 mutation identified, which one?	☐ R127P ☐ D140E ☐ P154L	☐ A169T ☐ E318D ☐ Other (specify)	6063734	Indicate the specific RNF43 mutation identified. Note: If the RNF43 mutation is not listed, proceed to Question 73a, otherwise, skip to Question 74.
73a	Other RNF43 mutation(s)		_	6101686	If the RNF43 mutation identified is not provided in the previous list, specify the RNF43 mutation.
74	Was SMAD4 IHC performed?	☐ Yes ☐ No ☐ Unknown		6063646	Indicate whether SMAD4 protein expression by immunohistochemistry (IHC) analysis was performed.  Note: If not performed, skip to Question 76.
75	SMAD4 expression by IHC	☐ Positive☐ Negative☐ Equivocal		6063676	Indicate the status of SMAD4 protein expression as determined by immunohistochemistry (IHC).
Primary Tun	nor Sample Information				
76	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No			If yes, proceed to question 77, otherwise, skip to Question 93.
77	Primary tumor biospecimen ordinal			6584265	Please provide a number to identify which biospecimen this is in the sequence. Note: This number should be "1".
78	CMDC sample ID			6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
79	BPC submitter ID (if available)			6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
80	Sample represents primary diagnosis?	☐ Yes ☐ No		6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3?  Note: If no, continue to Question 81, otherwise, skip to Question 82.
81	Specify the ICD-10 code			3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
82	Tumor tissue sample preservation method	☐ Cryopreserved☐ FFPE☐ Frozen☐ OCT☐ Snap frozen		5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
83	Anatomic site of tumor from which model was derived	☐ Pancreatic head ☐ Pancreatic body ☐ Pancreatic tail ☐ Liver	☐ Lung ☐ Lymph node ☐ Peritoneum ☐ Other (specify)	6033148	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI.  Note: If the tissue or organ of origin is not listed, proceed to Question 83a. Otherwise, skip to Question 84.
83a	Other anatomic site from which the tumor was obtained			5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
84	Method of cancer sample procurement	☐ Core needle biopsy☐ Distal partial pancr☐ Fine needle aspirat☐ Paracentesis☐ Whipple procedure☐ Other method (spe	eatectomy cion biopsy	3103514	Provide the procedure performed to obtain the primary tumor tissue.  Note: If the method of procurement is not listed, proceed to Question 84a, otherwise, skip to Question 85.

## **Enrollment: Pancreas**

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Tissue Source Site (TSS) Name: _	HCMI Identifier (ID3):
Completed By:	Completion Date (MM/DD/YYYY):

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
84a	Specify the other method		2006730	Specify the procedure performed to
	of tumor sample			obtain the primary tumor tissue, if not
	procurement			included in the previous list.
85	Number of days from		3288495	Provide the number of days from the
	index date to date of			index date to the date of the procedure
	tumor sample			that produced the tumor tissue
86	procurement Tumor tissue tune	□ Drimor.	3288124	submitted for HCMI.
86	Tumor tissue type	☐ Primary ☐ Additional Primary	3288124	Provide the primary tumor tissue type for this sample.
		□ NOS		Tor this sample.
Primary Tur	nor Model Information	L 1103	1	<u> </u>
87	Primary model		6594596	Please provide a number to identify
	biospecimen ordinal			which biospecimen this is in the
				sequence. Note: This number is expected
				to be "1".
88	CMDC model ID		6586036	Please provide the CMDC model ID
				for this sample as it will appear on
		<del></del>		tubes and the Sample Submission Form
				transmitted to the BPC.
89	BPC submitter ID (if		6584919	Please provide the BPC-generated ID for
	available)			this sample as it will appear on the
				Sample Submission Form transmitted to
00	NA a dal manusa a nata	Пусс	CE04730	the BPC.
90	Model represents	│ □ Yes │ □ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
91	primary diagnosis?  Model's primary tumor	l NO	6586035	Enter the CMDC Sample ID of the
91	tissue CMDC sample ID		0380033	PRIMARY TUMOR TISSUE from which
	tissue civibe sample ib			this model is derived.
92	Model's primary tumor		6584265	Enter the biospecimen ordinal of the
	biospecimen ordinal			PRIMARY TUMOR TISSUE from which
				this model is derived.
Treatment I	nformation		u.	
93	History of neoadjuvant	□ No	3382737	Indicate whether the patient received
	treatment	Yes; radiation prior to resection		neoadjuvant radiation or
		☐ Yes; pharmaceutical treatment prior to		pharmaceutical treatment.
		resection		Note: Radiation therapy is addressed in
		☐ Yes; both radiation and pharmaceutical		Questions 101-102. Pharmaceutical therapy is addressed in Questions 95-100.
		treatment prior to resection		is dudressed in Questions 93-100.
0.4	N. P.	Unknown	5022020	
94	Neoadjuvant	☐ Cytotoxic chemotherapy ☐ Hormonal	5832928	Select all neoadjuvant chemotherapy
	chemotherapy type			types that were administered to the
		☐ Immunotherapy (cellular and immune checkpoint)		patient.  Note: Cytotoxic chemotherapy is addressed
		☐ Targeted therapy (small molecule		in Questions 95-96. Immunotherapy is
		inhibitors and targeted antibodies)		addressed in Questions 97-98. Targeted
		□ Not applicable		therapy is addressed in Questions 99-100.
95	Neoadjuvant	☐ 5-Fluorouracil	2853313	Select all chemotherapeutics used for
	chemotherapeutic	☐ Albumin-bound		neoadjuvant therapy.
	regimen	Paclitaxel		Note: If neoadjuvant chemotherapy was
	-	☐ Capecitabine abraxane		not given, skip to Question 97. If the
		☐ Cisplatin ☐ Irinotecan		neoadjuvant chemotherapeutic regimen is
		☐ Docetaxel ☐ Irinotecan		not listed, proceed to Question 95a, otherwise, skip to Question 96.
		☐ Folfirinox liposome		סנוופו שופב, פגוף נט עמפטנטוו פס.
		(Oxaliplatin + 🔲 Oxaliplatin		
		Leucovorin +		
		Irinotecan + 5- ☐ Other (specify)		
		FU)		
		☐ Gemcitabine	<u> </u>	

	Enrollment: Pancreas	To the last	A THE	20	6	1
Tissue Source Site (TSS) Name: _	HCMI Identifier (ID3):	<b>169</b>	2	38		T
Completed By:	Completion Date (MM/DD/YYYY):	100	6 8	3000		

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
95a	Other neoadjuvant		62694	If the neoadjuvant therapy is not
	chemotherapeutic			included in the provided list, specify
	regimen			neoadjuvant therapies administered.
96	Days to neoadjuvant		5102411	Provide the number of days from index
	chemotherapy treatment			date to the date of treatment with
	from index date			neoadjuvant chemotherapy.
97	Immunotherapy name,		2953828	Provide the name of the
	specify			immunotherapy administered to the
				patient. Note: If immunotherapy was not
				administered, skip to Question 99.
98	Days to immunotherapy		5102411	Provide the number of days from the
	treatment from index			index date to the date of treatment
	date		5000110	with immunotherapy.
99	Targeted Therapy		6033149	Select the targeted molecular therapy
		☐ Erlotinib		administered to the patient.
		☐ Other (specify)		Note: If targeted therapy was not given, proceed to Question 101. If the targeted
		D other (speemy)		therapy is not listed, proceed to Question
				99a, otherwise, skip to Question 100.
99a	Specify targeted therapy		4308476	Provide the name of the targeted
				therapy administered to the patient.
100	Days to targeted therapy		5102411	Provide the number of days from the
	treatment from index			index date to the date of treatment
	date			with targeted therapy.
101	Radiation therapy	☐ 2D conventional	3028890	Provide the type of radiation therapy
	administered type	☐ 3D conformal		that was administered to the patient.
		☐ Brachytherapy HDR		Note: If radiation therapy was not
		☐ Brachytherapy LDR		administered, proceed to Question 103. If
		☐ IMRT		the radiation therapy is not listed, proceed
		☐ Proton Beam		to Question 101a, otherwise, skip to Question 102.
		☐ Stereotactic Body RT		Question 102.
		☐ Stereotactic Radiosurgery		
		☐ WBRT		
		☐ Other (specify)		
		☐ Unspecified		
		☐ Not applicable		
101a	Other radiation therapy		2195477	If the radiation therapy type is not
		·		included in the provided list, specify the
				type.
102	Days to radiation		5102411	Provide the number of days from the
	treatment from index	·		index date to the date of treatment
	date			with radiation therapy.
	Recurrent Tumor Biospecimo	en Information	1	
103	Are you submitting a			Indicate whether a
	metastatic/recurrent			metastatic/recurrent tumor
	tumor tissue sample?	Yes		biospecimen was collected for this ID3
		□ No		case. Note: If yes, proceed to Question 104.
				If submitting an OTHER tissue sample,
			270-5-5	proceed to Question 194.
104	Metastatic/recurrent		6584266	Please provide a number to identify
	tissue biospecimen			which biospecimen this is in the
	ordinal			sequence. Note: The first biospecimen
				should be number "1", the second should be
105	CMDC tissue ID		6586035	number "2", etc.  Please provide the CMDC sample ID for
103	CIVIDE USSUE ID		0300033	this biospecimen as it will appear on
				tubes and the Sample Submission Form
				transmitted to the BPC.
	<u> </u>	<u> </u>		transmitted to the BFC.

	Enrollment: Pancreas	Park I	
Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):		56
Completed By:	Completion Date (MM/DD/YYYY):	-	

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
106	BPC submitter ID (if available)		6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
107	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
108	Number of days from index date to date of diagnosis of metastasis/ recurrence		6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
109	Method of metastatic/ recurrent cancer sample procurement	<ul> <li>□ Core needle biopsy</li> <li>□ Distal partial pancreatectomy</li> <li>□ Fine needle aspiration biopsy</li> <li>□ Paracentesis</li> <li>□ Whipple procedure</li> <li>□ Other (specify)</li> </ul>	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue.  Note: If the method of procurement is not listed, proceed to Question 109a, otherwise, skip to Question 110.
109a	Other method of cancer sample procurement		6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
110	Number of days from index date to date of metastatic/ recurrent sample procurement		3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
111	Metastatic/ recurrent site	☐ Pancreatic head ☐ Lung ☐ Pancreatic body ☐ Lymph node ☐ Pancreatic tail ☐ Peritoneum ☐ Liver ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived.  Note: If the metastatic/recurrent site is not listed, proceed to Question 111a, otherwise, skip to Question 112.
111a	Other metastatic/ recurrent site	□ Abdomen       □ Other ill-defined         □ Accessory       sites         sinus       □ Ovary         □ Adrenal gland       □ Palate         □ Anus       □ Penis         □ Bladder       □ Peripheral nerves         □ Bone       and autonomic         □ Breast       nervous system of         □ Connective,       trunk         subcutaneous       □ Peritoneum         and other soft       □ Pharynx         tissues       □ Pituitary gland         □ Esophagus       □ Prostate gland         □ Eye       □ Rectosigmoid         □ Gallbladder       junction         □ Gallbladder       junction         □ Head, face or       □ Retroperitoneum         neck       □ Skin         □ Heart       □ Small intestine         □ Kidney       □ Spleen         □ Lip       □ Stomach         □ Liver       □ Testis         □ Lung       □ Thymus         □ Lymph node       □ Thyroid gland         □ Male genital       □ Tongue         organs       □ Tonsil	3128033	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.

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V1.0	Enrollment: Pancreas	
Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):	
Completed By:	Completion Date (MM/DD/YYYY):	

		□ Mediastinum       □ Trachea         □ Meninges       □ Unknown primary         □ Mouth       □ Urinary system         □ Nasal cavity       □ Uterus         □ Nasopharynx       □ Vagina         □ Nervous       □ Vulva         system       □ Oropharynx		
112	Site of relapse	<ul><li>□ Local</li><li>□ Regional</li><li>□ Distant</li><li>□ Not applicable</li></ul>	2002506	If the primary tumor relapsed, provide the site of relapse.
113	ICD-10 code		3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
114	ICD-O-3 histology code		3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
115	Maintenance and/or consolidation therapy administered prior to collection of metastatic/recurrent tissue		6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
116	Days to start of maintenance and/or consolidation therapy from index date		5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
117	Days to last known administration date of maintenance and/or consolidation therapy from index date		5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
118	Is the patient still receiving treatment?		6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
119	Disease status	<ul><li>□ No evidence of disease</li><li>□ Progressive disease</li><li>□ Stable disease</li><li>□ Unknown</li></ul>	2188290	Provide the disease status following maintenance and/or consolidation therapy.
120	Number of peripancreatic lymph nodes tested at surgery		6050944	Provide the total number of peripancreatic lymph nodes tested for the presence of pancreatic cancer cells.
121	Number of positive peripancreatic lymph nodes	☐ 0 ☐ 1-3 ☐ ≥4 ☐ Unknown	5983082	Select the numeric range of the number of peripancreatic lymph nodes that tested positive for the presence of pancreatic cancer cells.
122	Has the CEA level of the patient been determined?	☐ Yes ☐ No	3107563	Indicate whether the Carcinoembryonic antigen (CEA) level of the patient has been determined.  Note: If the patient's CEA level has not been determined, skip to Question 125.
123	CEA level		2752	Provide the patient's carcinoembryonic (CEA) level (ng/ml).

	Enrollment: Pancreas	
Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):	
Completed By:	Completion Date (MM/DD/YYYY):	

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
124	CEA level upper limit of normal value		2002247	Provide the numeric laboratory value (ng/ml) representing the upper level of the normal range of values for carcinoembryonic antigen (CEA) in blood used to comparatively reference the patient's lab result.
125	Was tumor marker CA- 19-9 test performed?	☐ Yes ☐ No ☐ Unknown	2891778	Indicate whether the patient's tumor marker CA-19-9 value was assessed.  Note: If the CA-19-9 test was not performed, skip to Question 127.
126	What was the CA-19-9 value?		65302	Provide the patient's CA-19-9 level.
Metastatic/	Recurrent Tumor Sample: Cli	inical Molecular Analyses		L
127	Was KRAS mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6060079	Indicate whether KRAS mutation analysis was performed.  Note: If not performed, skip to Question 130.
128	Was a mutation in KRAS identified	☐ Yes ☐ No	6060081	Indicate whether a mutation in KRAS was identified through mutation analysis. Note: If mutation was not identified, skip to Question 130.
129	If KRAS mutation identified, which one?	□ G12A □ G12V □ G13V □ Q61L □ G12C □ G13D □ Q61H □ G12D □ G13R □ A146T □ G12S □ G13A □ Other (specify)	6060083	Indicate the specific KRAS mutation identified.  Note: If the KRAS mutation is not listed, proceed to Question 129a, otherwise, skip to Question 130.
129a	Other KRAS mutation(s)		6101691	If the KRAS mutation identified is not provided in the previous list, specify the KRAS mutation.
130	Was TP53 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063448	Indicate whether TP53 mutation analysis was performed.  Note: If not performed, skip to Question 132.
131	If TP53 mutation identified, which one?	□ R175H       □ R248Q       □ R273H         □ R213L       □ R248W       □ R273L         □ Y220C       □ G266E       □ R282G         □ C238Y       □ G266V       □ R282W         □ G245D       □ V272M       □ Other         □ G245S       □ R273C       (specify)	6063731	Indicate the specific TP53 mutation identified.  Note: If the TP53 mutation is not listed, proceed to Question 131a, otherwise, skip to Question 132.
131a	Other TP53 mutation(s)		6101683	If the TP53 mutation identified is not provided in the previous list, specify the TP53 mutation.
132	Was CDKN2A mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063449	Indicate whether CDKN2A mutation analysis was performed.  Note: If not performed, skip to Question 135.
133	Was a mutation in CDKN2A identified?	☐ Yes ☐ No	6063534	Indicate whether a mutation in CDKN2A was identified through mutation analysis.  Note: If mutation was not identified, skip to Question 135.
134	If CDKN2A mutation identified, which one?	□ A30V       □ H83Y       □ A147T         □ V51D       □ D108H       □ A148T         □ V51I       □ D108Y       □ Other         □ H83P       □ L130Q       (specify)	6063732	Indicate the specific CDKN2A mutation identified.  Note: If the CDKN2A mutation is not listed, proceed to Question 134a, otherwise, skip to Question 135.
134a	Other CDKN2A mutation(s)		6101684	If the CDKN2A mutation identified is not provided in the previous list, specify the CDKN2A mutation.

	Enrollment: Pancreas	
Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):	
Completed By:	Completion Date (MM/DD/YYYY):	

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
135	Was GNAS mutation	☐ Yes	6063450	Indicate whether GNAS mutation
	analysis performed?	□ No		analysis was performed. Note: If not
		☐ Unknown		performed, skip to Question 138.
136	Was a mutation in GNAS		5983161	Indicate whether a mutation in GNAS
	identified?	☐ Yes		was identified through mutation
		□ No		analysis. Note: If mutation was not
				identified, skip to Question 138.
137	If GNAS mutation	☐ Q125R ☐ R201S ☐ Q227P	6063733	Indicate the specific GNAS mutation
	identified, which one?	□ R160C □ Q227E □ Q227R		identified. Note: If the GNAS mutation is
		□ R201C □ Q227L □ Other		not listed, proceed to Question 137a,
		☐ R201H ☐ Q227E (specify)		otherwise, skip to Question 138.
137a	Other GNAS mutation(s)		6101685	If the GNAS mutation identified is not
				provided in the previous list, specify the
				GNAS mutation.
138	Was RNF43 mutation	☐ Yes	6063451	Indicate whether RNF43 mutation
	analysis performed?	□ No		analysis was performed. Note: If not
		□ Unknown		performed, skip to Question 141.
139	Was a mutation in RNF43		5983286	Indicate whether a mutation in RNF43
	identified?	☐ Yes		was identified through mutation
		□ No		analysis. Note: If mutation was not
				identified, skip to Question 140.
140	If RNF43 mutation		6063734	Indicate the specific RNF43 mutation
	identified, which one?	□ R127P □ A169T		identified.
	·	□ D140E □ E318D		Note: If the RNF43 mutation is not listed,
		☐ P154L ☐ Other (specify)		proceed to Question 140a, otherwise, skip
				to Question 141.
140a	Other RNF43 mutation(s)		6101686	If the RNF43 mutation identified is not
		<del></del>		provided in the previous list, specify the
				RNF43 mutation.
141	Was SMAD4 IHC	□ Yes	6063646	Indicate whether SMAD4 protein
	performed?	□ No		expression by immunohistochemistry
		☐ Unknown		(IHC) analysis was performed. Note: If
		- Olikilowii		not performed, skip to Question 143.
142	SMAD4 expression by IHC	☐ Positive	6063676	Indicate the status of SMAD4 protein
		☐ Negative		expression as determined by
		☐ Equivocal		immunohistochemistry (IHC).
		•		
		Biospecimen Information (if applicable)		<u></u>
143	Are you submitting an			A biospecimen obtained from a single
	additional metastatic/			site at a single timepoint in progression
	recurrent tumor tissue			that is portioned for both sequencing
	sample?			and model generation counts as 1 single
				tumor specimen. A biospecimen
		☐ Yes		obtained from another site or at a later
		□ No		timepoint in progression that is
				portioned for both sequencing and
				model generation counts as a second
				single tumor specimen.
				Note: If yes, proceed to Question 144,
				otherwise, skip to Question 183.
144	Metastatic/recurrent		6584266	Please provide a number to identify
	tissue biospecimen			which biospecimen this is in the
	ordinal			sequence. The first biospecimen should
				be number "1," the second should be
				number "2," etc.
145	CMDC tissue ID		6586035	Please provide the CMDC sample ID for
				this biospecimen as it will appear on
				tubes and the Sample Submission Form
			]	transmitted to the BPC.

	Enrollment: Pancreas	To the last	The second	6	
Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):	CKO SA	45%		
Completed By:	Completion Date (MM/DD/YYYY):	100			

Question	Question Text	Data Entry Options		CDE ID	Instruction Text
146	BPC submitter ID (if available)		-	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
147	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved☐ FFPE☐ Frozen	☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
148	Number of days from index date to date of diagnosis of additional metastasis/ recurrence		-	6132218	Provide the number of days from the index date to the date of diagnosis of additional metastatic/recurrent disease.
149	Method of metastatic/ recurrent cancer sample procurement	☐ Core needle biop☐ Distal partial pan☐ Fine needle aspir☐ Paracentesis☐ Whipple procedu☐ Other (specify)	createctomy ation biopsy	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue.  Note: If the method of procurement is not listed, proceed to Question 149a, otherwise, skip to Question 150.
149a	Other method of cancer sample procurement		-	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
150	Number of days from index date to date of metastatic/ recurrent sample procurement		-	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
151	Metastatic/ recurrent site	☐ Pancreatic head ☐ Pancreatic body ☐ Pancreatic tail ☐ Liver	☐ Lung ☐ Lymph node ☐ Peritoneum ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived.  Note: If the metastatic/recurrent site is not listed, proceed to Question 151a, otherwise, skip to Question 152.
151a	Other metastatic/ recurrent site	□ Abdomen □ Accessory sinus □ Adrenal gland □ Anus □ Appendix □ Bladder □ Bone □ Breast □ Connective, subcutaneous and other soft tissues □ Esophagus □ Eye □ Gallbladder □ Gum □ Head, face or neck □ Heart □ Kidney □ Larynx □ Lip □ Liver □ Lung □ Lymph node	□ Other ill-defined sites □ Ovary □ Palate □ Pancreas □ Penis □ Peripheral nerves and autonomic nervous system of trunk □ Peritoneum □ Pharynx □ Pituitary gland □ Prostate gland □ Rectosigmoid junction □ Renal pelvis □ Retroperitoneum □ Skin □ Small intestine □ Spinal cord □ Spleen □ Stomach □ Testis □ Thymus □ Thyroid gland □ Tongue	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.

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	Enr	rollment: Pancre	as	1	
Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):		(10)		
Completed By:	Completion Date (MM/DD/YYYY):				
	☐ Male genital	П Tonsil			

		☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oronbarynx	☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva		
152	Site of relapse	☐ Oropharynx ☐ Local		2002506	If the primary tumor relapsed, provide
132	Site of relapse	☐ Regional ☐ Distant ☐ Not applicable		2002300	the site of relapse.
153	ICD-10 code		-	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
154	ICD-O-3 histology code		-	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
155	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue		-	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
156	Days to start of maintenance and/or consolidation therapy from index date		-	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
157	Days to last known administration date of maintenance and/or consolidation therapy from index date		-	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
158	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown		6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
159	Disease status	☐ No evidence of o ☐ Progressive dise ☐ Stable disease ☐ Unknown		2188290	Provide the disease status following maintenance and/or consolidation therapy.
160	Number of peripancreatic lymph nodes tested at surgery		-	6050944	Provide the total number of peripancreatic lymph nodes tested for the presence of pancreatic cancer cells.
161	Number of positive peripancreatic lymph nodes	□ 0 □ 1-3 □ ≥4 □ Unknown		5983082	Select the numeric range of the number of peripancreatic lymph nodes that tested positive for the presence of pancreatic cancer cells.
162	Has the CEA level of the patient been determined?	☐ Yes ☐ No		3107563	Indicate whether the Carcinoembryonic antigen (CEA) level of the patient has been determined.  Note: If the patient's CEA level has not been determined, skip to Question 165.
163	CEA level		_	2752	Provide the patient's carcinoembryonic (CEA) level (ng/ml).

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V-1.0	Enrollment: Pancreas	
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
164	CEA level upper limit of normal value		2002247	Provide the numeric laboratory value (ng/ml) representing the upper level of the normal range of values for carcinoembryonic antigen (CEA) in blood used to comparatively reference the patient's lab result.
165	Was tumor marker CA- 19-9 test performed?	☐ Yes ☐ No ☐ Unknown	2891778	Indicate whether the patient's tumor marker CA-19-9 value was assessed.  Note: If the CA-19-9 test was not performed, skip to Question 167.
166	What was the CA-19-9 value?		65302	Provide the patient's CA-19-9 level.
Additional I	//etastatic/Recurrent Tumor	Sample: Clinical Molecular Analyses		
167	Was KRAS mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6060079	Indicate whether KRAS mutation analysis was performed.  Note: If not performed, skip to Question 170.
168	Was a mutation in KRAS identified	☐ Yes ☐ No	6060081	Indicate whether a mutation in KRAS was identified through mutation analysis. Note: If mutation was not identified, skip to Question 170.
169	If KRAS mutation identified, which one?	□ G12A □ G12V □ G □ G12C □ G13D □ Q □ G12D □ G13R □ A: □ G12R □ G13C □ O □ G12S □ G13A (s	61L 61H L46T	Indicate the specific KRAS mutation identified.  Note: If the KRAS mutation is not listed, proceed to Question 169a, otherwise, skip to Question 170.
169a	Other KRAS mutation(s)		6101691	If the KRAS mutation identified is not provided in the previous list, specify the KRAS mutation.
170	Was TP53 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063448	Indicate whether TP53 mutation analysis was performed.  Note: If not performed, skip to Question 172.
171	If TP53 mutation identified, which one?	□ R175H       □ R248Q       □ R2         □ R213L       □ R248W       □ R2         □ Y220C       □ G266E       □ R2         □ C238Y       □ G266V       □ R2         □ G245D       □ V272M       □ O         □ G245S       □ R273C       (s	273L 282G 282W	Indicate the specific TP53 mutation identified.  Note: If the TP53 mutation is not listed, proceed to Question 171a, otherwise, skip to Question 172.
171a	Other TP53 mutation(s)		6101683	If the TP53 mutation identified is not provided in the previous list, specify the TP53 mutation.
172	Was CDKN2A mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063449	Indicate whether CDKN2A mutation analysis was performed.  Note: If not performed, skip to Question 176.
173	Was a mutation in CDKN2A identified?	☐ Yes ☐ No	6063534	Indicate whether a mutation in CDKN2A was identified through mutation analysis.  Note: If mutation was not identified, skip to Question 175.
174	If CDKN2A mutation identified, which one?	□ A30V □ H83Y □ A30V □ D108H □ A30V □ D108H □ A30V □ D108Y □	148T ther pecify)	Indicate the specific CDKN2A mutation identified.  Note: If the CDKN2A mutation is not listed, proceed to Question 174a, otherwise, skip to Question 175.
174a	Other CDKN2A mutation(s)		6101684	If the CDKN2A mutation identified is not provided in the previous list, specify the CDKN2A mutation.

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Question	Question Text	Data Entry Options		CDE ID	Instruction Text
175	Was GNAS mutation	☐ Yes		6063450	Indicate whether GNAS mutation
	analysis performed?	□ No			analysis was performed. Note: If not
176	Was a mutation in GNAS	□ Unknown		5983161	performed, skip to Question 178.  Indicate whether a mutation in GNAS
176	identified?	☐ Yes		3903101	was identified through mutation
	identified.	□ No			analysis. Note: If mutation was not
					identified, skip to Question 178.
177	If GNAS mutation	1 1 2 11 2 11 2		6063733	Indicate the specific GNAS mutation
	identified, which one?	∐ R160C	Q227R		identified. Note: If the GNAS mutation is
		□ R201C □ Q227L □ Q227L □ R201H	Other (specify)		not listed, proceed to Question 177a, otherwise, skip to Question 178.
177a	Other GNAS mutation(s)	L KZOIII		6101685	If the GNAS mutation identified is not
2770				0101000	provided in the previous list, specify the
					GNAS mutation.
178	Was RNF43 mutation	☐ Yes		6063451	Indicate whether RNF43 mutation
	analysis performed?	□ No			analysis was performed. Note: If not
470	)	□ Unknown		5000000	performed, skip to Question 181.
179	Was a mutation in RNF43 identified?	☐ Yes		5983286	Indicate whether a mutation in RNF43 was identified through mutation
	identined:	□ No			analysis. Note: If mutation was not
					identified, skip to Question 181.
180	If RNF43 mutation	□ R127P		6063734	Indicate the specific RNF43 mutation
	identified, which one?	□ D140E			identified. Note: If the RNF43 mutation is
		□ P154L			not listed, proceed to Question 180a, otherwise, skip to Question 181.
		□ A169T □ E318D			otherwise, skip to Question 181.
		☐ Other (specify)			
180a	Other RNF43 mutation(s)	a other (speemy)		6101686	If the RNF43 mutation identified is not
	, ,				provided in the previous list, specify the
					RNF43 mutation.
181	Was SMAD4 IHC	☐ Yes		6063646	Indicate whether SMAD4 protein
	performed?	□ No			expression by immunohistochemistry
		☐ Unknown			(IHC) analysis was performed. Note: If not performed, skip to Question 183.
182	SMAD4 expression by IHC	☐ Positive		6063676	Indicate the status of SMAD4 protein
		☐ Negative			expression as determined by
		☐ Equivocal			immunohistochemistry (IHC).
	Recurrent Tumor Model Info	rmation	1.	6504507	
183	METASTATIC/ RECURRENT model		'	6594587	Please provide a number to identify which biospecimen this is in the
	biospecimen ordinal				sequence. Note: The first biospecimen
					should be number "1," the second should be
	0.450			.=	number "2," etc.
184	CMDC model ID			6586036	Please provide the CMDC model ID for this sample as it will appear
					on tubes and the Sample Submission
					Form transmitted to the BPC.
185	BPC submitter ID (if		(	6584919	Please provide the BPC-generated ID
	available)				for this sample as it will appear on the
		·			Sample Submission Form transmitted
400	Mandalla BAETACTATIC/			CE0C025	to the BPC.
186	Model's METASTATIC/ RECURRENT tumor tissue		6	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from
	CMDC sample ID				which this model is derived.
	22 0 00ріс 12				
187	Model's METASTATIC/		(	6584266	Enter the biospecimen ordinal
	RECURRENT tumor tissue				of the METASTATIC/RECURRENT tissue
	biospecimen ordinal				from which this model is derived.

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M/DD/YYYY):	

Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
		cimen Tumor Model Information (if applicable)		mistraction rext
188	METASTATIC/ RECURRENT model biospecimen ordinal		6594587	Please provide a number to identify which biospecimen this is in the sequence.  Note: The first biospecimen should be number "1," the second should be number "2," etc.
189	CMDC model ID		6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
190	BPC submitter ID (if available)		6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
191	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID		6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
192	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal		6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biosp	ecimen Information	I	l	
193	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case.  Note: If yes, proceed to Question 194.
194	OTHER tissue biospecimen ordinal		6584267	Please provide a number to identify which biospecimen this is in the sequence.  Note: The first biospecimen should be number "1," the second should be number "2," etc.
195	CMDC sample ID		6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
196	BPC submitter ID (if available)		6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
197	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
198	Other method of cancer sample procurement	☐ Core needle biopsy ☐ Distal partial pancreatectomy ☐ Fine needle aspiration biopsy ☐ Paracentesis ☐ Whipple procedure ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue.  Note: If the method of procurement is not listed, proceed to Question 198a, otherwise, skip to Question 199.
198a	Specify method of OTHER tissue sample procurement		6587399	Specify the procedure performed to obtain the OTHER tissue.

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Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):	WO SH	1	3		1
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Question	Question Text	Data Entry Options		CDE ID	Instruction Text
199	Number of days from	July Specials		3288495	Provide the number of days from the
	index date to date of				index date to the date of the procedure
	OTHER sample				that produced the OTHER tissue
	procurement				submitted for HCMI.
200	Tissue type			64784	Indicate the OTHER tissue type.
		☐ Non-malignant			Note: If the OTHER tissue type is not listed,
		☐ Other (specify)			proceed to Question 200a, otherwise, skip
					to Question 201.
200a	Specify tissue type			64785	Specify the OTHER tissue type if not in
	Anatomic site of OTHER			6696813	the provided list.  Select the site from which the OTHER
201	tissue	☐ Pancreatic head	☐ Lung	0090813	tissue used to develop the model was
201	tissue	☐ Pancreatic body	. 0		derived.
		☐ Pancreatic tail	☐ Peritoneum		Note: If the OTHER tissue site is not listed,
		☐ Liver	☐ Other (specify)		proceed to Question 201a, otherwise, skip
			(1 //		to Question 202.
201a	Specify anatomic site of	☐ Abdomen	☐ Other ill-defined	6584916	Specify the site of OTHER tissue, if not
	OTHER tissue	☐ Accessory	sites		in the previous list.
		sinus	☐ Ovary		
		☐ Adrenal gland	□ Palate		
		☐ Anus	☐ Pancreas		
		☐ Appendix	☐ Penis		
		□ Bladder	☐ Peripheral nerves		
		☐ Bone	and autonomic		
		☐ Breast	nervous system of		
		☐ Connective, subcutaneous	trunk  Peritoneum		
		and other soft	☐ Pharynx		
		tissues	☐ Pituitary gland		
		☐ Esophagus	☐ Prostate gland		
		☐ Eye	☐ Rectosigmoid		
		☐ Gallbladder	junction		
		☐ Gum	☐ Renal pelvis		
		☐ Head, face or	☐ Retroperitoneum		
		neck	☐ Skin		
		☐ Heart	☐ Small intestine		
		☐ Kidney	☐ Spinal cord		
		☐ Larynx	☐ Spleen		
		☐ Lip	☐ Stomach		
		☐ Liver	☐ Testis		
		☐ Lung	☐ Thymus		
		☐ Lymph node	☐ Thyroid gland		
		☐ Male genital	☐ Tongue		
		organs	☐ Tonsil		
		☐ Mediastinum	☐ Trachea		
		☐ Meninges	☐ Unknown primary		
		☐ Mouth	☐ Urinary system		
		☐ Nasal cavity	☐ Uterus		
		☐ Nasopharynx☐ Nervous	☐ Vagina		
		system	□ Vulva		
		□ Oropharynx			
202	ICD-10 code	Orophiarynx		3226287	Provide the ICD-10 code for the OTHER
202	ICD-TO COME			3220201	tissue used to generate the model
					submitted to HCMI.
203	ICD-O-3 histology code			3226275	Provide the ICD-O-3 histology code
	o o miscology code			3223273	describing the morphology of the
					OTHER tissue used to generate the
					model submitted to HCMI.
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# **Enrollment: Pancreas**

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Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
	OTHER biospecimen Informat	іоп (іт арріісаріе)		Indicate whether an additional OTUER
204	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case.  Note: If yes, proceed to Question 205, otherwise, skip to Question 215.
205	OTHER tissue biospecimen ordinal		6584267	Please provide a number to identify which biospecimen this is in the sequence. Note: The first biospecimen should be number "1," the second should be number "2," etc.
206	CMDC sample ID		6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
207	BPC submitter ID (if available)		6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
208	OTHER tissue sample preservation method	☐ Cryopreserved ☐ OCT ☐ Snap froze	5432521 n	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
209	Other method of cancer sample procurement	☐ Core needle biopsy ☐ Distal partial pancreatectomy ☐ Fine needle aspiration biopsy ☐ Paracentesis ☐ Whipple procedure ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue.  Note: If the method of procurement is not listed, proceed to Question 209a, otherwise, skip to Question 210.
209a	Specify method of OTHER tissue sample procurement		6587399	Specify the procedure performed to obtain the OTHER tissue.
210	Number of days from index date to date of OTHER sample procurement		3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
211	Tissue type	□ Non-malignant □ Other (specify)	64784	Indicate the OTHER tissue type.  Note: If the OTHER tissue type is not listed, proceed to Question 211a, otherwise, skip to Question 212.
211a	Specify tissue type		64785	Specify the OTHER tissue type if not in the provided list.
212	Anatomic site of OTHER tissue	☐ Pancreatic head ☐ Lung ☐ Pancreatic body ☐ Lymph nod ☐ Pancreatic tail ☐ Peritoneur ☐ Liver ☐ Other (spe	n	Select the site from which the OTHER tissue used to develop the model was derived.  Note: If the OTHER tissue site is not listed, proceed to Question 212a, otherwise, skip to Question 213.
212a	Specify anatomic site of OTHER tissue	□ Abdomen □ Other ill-defi □ Accessory sites sinus □ Ovary □ Adrenal gland □ Palate □ Anus □ Pancreas □ Appendix □ Penis □ Bladder □ Peripheral ne □ Bone and autonom □ Breast nervous syste □ Connective, subcutaneous □ Peritoneum	erves nic	Specify the site of OTHER tissue, if not in the previous list.

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## **Enrollment: Pancreas**

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Tissue Source Site (TSS) Name: \_\_\_\_\_ HCMI Identifier (ID3): \_\_\_\_\_

Completed By: \_\_\_\_\_ Completion Date (MM/DD/YYYY): \_\_\_\_\_

213	ICD-10 code	and other soft tissues  Esophagus Eye Gallbladder Gum Head, face or neck Heart Kidney Larynx Lip Liver Lung Lymph node Male genital organs Mediastinum Meninges Mouth Nasal cavity Nasopharynx Nervous system Oropharynx	□ Pharynx □ Pituitary gland □ Prostate gland □ Rectosigmoid     junction □ Renal pelvis □ Retroperitoneum □ Skin □ Small intestine □ Spinal cord □ Spleen □ Stomach □ Testis □ Thymus □ Thyroid gland □ Tongue □ Tonsil □ Trachea □ Unknown primary □ Urinary system □ Uterus □ Vulva	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
214	ICD-O-3 histology code			3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the
Other Tissue	Model Information			1	model submitted to HCMI.
215	OTHER tissue model biospecimen ordinal		_	6594590	Please provide a number to identify which biospecimen this is in the sequence. Note: The first biospecimen should be number "1," the second should be number "2," etc.
216	CMDC model ID		-	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
217	BPC submitter ID (if available)		-	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
218	Model's OTHER tissue CMDC sample ID		-	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
209	Model's OTHER tissue biospecimen ordinal		-	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
	Other Tissue Model Informati	ion (if applicable)		1	
220	OTHER tissue model biospecimen ordinal		-	6594590	Please provide a number to identify which biospecimen this is in the sequence. Note: The first biospecimen should be number "1," the second should be number "2," etc.

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Tissue Source Site (TSS) Name: _	HCMI Identifier (ID3):	135
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
221	CMDC model ID		6586036	Please provide the CMDC model ID
				for this sample as it will appear on
				tubes and the Sample Submission Form
				transmitted to the BPC.
222	BPC submitter ID (if		6584919	Please provide the BPC-generated ID
	available)			for this sample as it will appear on the
				Sample Submission Form transmitted
				to the BPC.
223	Model's OTHER tissue		6586035	Enter the CMDC Sample ID of the
	CMDC sample ID			OTHER tissue from which this model is
				derived.
224	Model's OTHER tissue		6584267	Enter the biospecimen ordinal of the
	biospecimen ordinal			OTHER tissue from which this model is
				derived.